Date of Facsimile: March 16, 2004 Atty. Docket No. CST-138CIP2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Comb *et al.*		
ASSIGNEE:	CELL SIGNALING TECHNOLOGY, INC.		
SERIAL NUMBER:	10/014,485	EXAMINER:	P. Ponnaluri
FILING DATE:	November 13, 2001	ART UNIT:	1639
FOR:	PRODUCTION OF MOTIF-SPECIFIC AND CONTEXT-INDEPENDENT ANTIBODIES USING PEPTIDE LIBRARIES AS ANTIGENS		

March 16, 2004
Beverly, Massachusetts

Mail Stop NON-FEE AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT (37 C.F.R. §1.143; §1.111)

This paper is in response to the September 17, 2003 Office Action and Restriction Requirement issued in the above-identified patent application. This Response is filed following an in-person interview with the Examiner, on March 10, 2003, discussing the outstanding restriction requirement. A Petition for a three (3) month extension of time under 37 C.F.R. §1.136(a) is enclosed herewith. The Commissioner is hereby authorized to charge the required fee (small entity) of $495.00, pursuant to 37 C.F.R. §1.17(a)(3), along with any other fees that may be due, to Deposit Account No. 50-1774, Ref. No. CST-138CIP2. With the extension, the present papers are due on or before March 17, 2004.

SUMMARY OF INTERVIEW

Pursuant to 37 C.F.R §1.133(b), Applicants provide the following summary of the in-person interview between the Examiner and the undersigned attorney, held on March 10, 2004. Also present was Dr. Roberto Polakiewicz, Ph.D., Director of Research at CELL SIGNALING TECHNOLOGY, INC., the assignee of the present application.

Applicants' attorney informed the Examiner that Applicants would, in this paper, voluntarily withdraw (without traverse) 22 of the 25 Groups of claims presently restricted, notwithstanding that Applicants' believe the restrictions are improper. Applicants' attorney informed the Examiner that Applicants would request reconsideration of the outstanding restriction requirement pertaining to the subject matter of Group II (claims 3-16) and Groups VII (claims 21-26, in part) and VIII (claims 21-26, in part). Applicants' attorney stated that this subject matter is related as method of production and product made. Applicants' attorney also informed the Examiner that the claims of Groups II, VII and VIII are in genus and preferred species format, and that Applicants would, in the present paper, voluntarily amend certain of these claims to more clearly define the features and characteristics of the presently claimed subject matter.

Regarding the subject matter of Group II and Groups VII/VIII, Applicants' attorney informed the Examiner that restriction between the product and method of production in the instant case was not proper, because no other suitable method for the production of the claimed product is presently known, thus one-way distinctiveness is not satisfied. Applicants' attorney also reminded the Examiner that restriction between the genus and preferred species claimed in these groups was not proper, since the class and subclass of search is identical for the subject matter of the claims within these Groups (class 435, subclass 331 for Group II (method); class 530, subclass 387.1 for Groups VII/VIII (product)). Applicants' attorney informed the Examiner that the Directors of USPTO Technology Center 1600 had recently reaffirmed, at a patent conference in Boston,[1] that Examiners should not make or maintain restriction requirements among subject matter having identical class and subclass, *unless* the Examiner has established by *clear and objective reasoning*, that a search – despite being within the same class/subclass – would still somehow unduly burden the Examiner. The Directors stated that a mere allegation

[1] USPTO Biotech Roadshow "Hot Topics in Biotechnology," February 27th in Boston, MA, co-sponsored by the Boston Patent Law Association. Technology Center 1600 Director Dr. Jasemine Chambers, Ph.D., J.D., presenting, as well as 1600 Quality Assurance Specialist, Brian Stanton.

by an Examiner of "undue burden" or that "separate searches would be required" is *not* a sufficient ground to make or maintain restriction.

Applicants' attorney discussed with the Examiner that unduly burdensome or completely different searching is not required in the present case, since searching for the terms "motif," "antibody," and "phosphorylated" and/or "modified" will readily turn up prior art relevant to the presently claimed genus/species subject matter, which is in identical class/subclass of search. Although the Examiner stated that she disagreed with the prohibition against making restrictions for subject matter in the same class and subclass of search, and disagreed with the recent instruction given by the Directors of Art Group 1600 that such restrictions should not be made or maintained, the Examiner agreed to reconsider the outstanding restriction requirement relating to Groups II, VII and VIII upon Applicants' filing of the present paper.

REQUEST FOR RECONSIDERATION

Applicants are presently withdrawing, without traverse, 22 of the 25 Groups of claims among which the Examiner has required restriction.[2] Applicants have further voluntarily cancelled certain claims within the remaining three groups to expedite prosecution the preferred subject matter presently claimed. Pursuant to 37 C.F.R. §1.143, Applicants respectfully request reconsideration of the outstanding restriction requirement with respect to the subject matter of the three remaining Groups II, VII, and VIII . These three groups are drawn to a preferred method of producing antibodies (pending claims 2-4 and 11-16) and to a preferred genus of antibodies (pending claims 21-26). Applicants have presently voluntarily amended pending claims 2-4, 11-16, and 21-26 in order to more clearly define the claimed subject matter in genus, sub-genus, and species form, and to more clearly define the features and characteristics of the preferred subject matter presently claimed (see below). In accordance with § 37 C.F.R. §1.143; 35 U.S.C. §121, Applicants hereby provisionally elect the subject matter of Group VII, and

[2] Although Applicants restate for the record that there are clearly not 25 independent and distinct inventions presently claimed.

provisionally elect the AKT consensus substrate motif species within Group VII (claim 24).

As discussed in more detail below, restriction between the subject matter of claims 2-4 and 11-16 (Group III – drawn to a method of producing a motif-specific, context-independent antibody) and the subject matter of claims 21-26 (Groups VII and VIII – drawn to motif-specific, context-independent antibodies produced) is improper because the method of production and antibodies produced are not distinct. Applicants are not aware of any other production methodology that, at the present time, is suitable for the production of the claimed antibodies. Therefore, the claimed antibodies cannot, *at the present time*, be produced by any suitable alternative methods.[3] The disclosed, and presently claimed, method for producing these novel antibodies is not obvious, nor can it be used to produce non- motif-specific, context-independent antibodies as disclosed in the specification. Accordingly, one-way distinctiveness is not satisfied, and the restriction between the subject matter of Group III and Groups VII and VIII is improper. *See* MPEP §806.05(f).

The restriction requirement between the subject matter of Group VII (claims 21-26, in part) and Group VIII (claims 21-26, in part) is similarly improper because the subject matter of these claims is in an identical class (530) and subclass (387.1). Accordingly, absent a clear, objective and supportable showing by the Examiner that a search of the claimed subject matter would be unduly burdensome – despite the identical class and subclass of the subject matter – the present restriction should not be made or maintained. *See* MPEP §803 (must be a "serious burden" on the examiner (not just *some* burden); MPEP §808.02 (related but distinct inventions should not be restricted if classification/field of search is the same and no indication of separate future classification); *see also* footnote 1 (guidance provided by Directors of Technology Center 1600, in which the present case lies). Clearly, the subject matter presently claimed can be adequately searched using only a few search terms, and does require multiple or unduly

[3] In the future, however, alternative methods of producing the novel antibodies first provided by the present invention may be developed. Antibodies produced by such alternative methods are within the scope of the presently claimed subject matter.

burdensome searching.

Moreover, the genus, subgenus, and species of antibodies to which claims 21-26 are drawn all share common essential characteristics and are connected in design, operation, and effect. The claimed antibodies are all designed to, and operate to, specifically bind short, recurring, phosphorylated motifs of a certain structure (comprising two to six invariant amino acids including at least one phosphorylated amino acid and optionally (but typically) one or more degenerate positions) that are important to signal transduction, and have the essential characteristic of to bind the motif in a plurality of peptides/proteins within an organism in which it recurs. Since the subject matter of the claims of groups VII and VIII share essential characteristics and are connected in design, operation, and effect (as further evidenced by their identical class/subclass of search (530, 387.1) they are not independent and distinct. Accordingly, the present restriction is improper and should be withdrawn. *See* MPEP §808.01.

Applicants respectfully request that the outstanding restriction of the subject matter of Groups II, VII, and VIII be withdrawn, and that Applicants are entitled to retain and prosecution the preferred subject matter of pending claims 2-4, 11-16, and 21-26 in the present case. Pursuant to 37 C.F.R. §1.141, Applicants are entitled to prosecute the reasonable number of species presently claimed in one application, subject to the requirement for a provisional species election, which Applicants have made.

AMENDMENTS UNDER 37 C.F.R. §§1.111, 1.121

This Amendment and Response includes the following sections on subsequent pages:
Amendments to Claims: are reflected in the listing of claims on pages 6-9 of this paper.
Remarks: pages 10-11 of this paper.

This Amendment complies with the requirements of the Revised Format of Amendments promulgated in the Revised Notice dated June 30, 2003 (effective July 30, 2003) [and at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/moreinfoamdtprac.htm], and with 37 C.F.R. §1.121. Separate marked-up versions of the specification and claims are not required.